K022555

AUG 2 6 2002

Special 510(k) Summary

Modification to Accolade™ C Femoral Stems

Proprietary Name:	Accolade™ C Femoral Stems
Common Name:	Femoral Hip Stems
Classification Name and Reference:	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3353
Proposed Regulatory Class:	Class II
Device Product Code:	87 LZO
Predicate Proprietary Name(s):	Accolade™ C Femoral Stem
Predicate Regulatory Class:	Class II
Predicate Product Code(s):	87 LZO
Submitted By:	Howmedica Osteonics Corp. 59 Route 17 Allendale, New Jersey 07401-1677 (201) 825-4900
Contact Information:	Debra Bing Phone: (201) 831-5413 Fax: (201) 831-6038
Date Summary Prepared:	August 15, 2002

Description/Technological Comparison

The subject Accolade™ C Femoral Stems are forged from cobalt chromium alloy. They are straight, neutral stems with medial collars. They come in 127° and 132° neck angles. Crescent shaped indentations on the anterior and posterior surfaces provide rotational stability and enhanced mechanical interlock of the cement. The lateral shoulder features a non-threaded hole for connection to an insertion tool. The distal tip of the stems features a recess for optional use

The subject Accolade™ C Femoral Stems differ from the predicate Accolade™ C Femoral Stems only in that they feature a recess in the distal tip to allow use with the predicate Howmedica Osteonics Universal Distal Spacers or Universal Distal Hole Plugs. All other design features, materials, and intended uses are the same as for the predicate Accolade™ C Femoral Stems.

Intended Use

The subject devices retain the same intended use as the predicate devices. The only difference is that the subject devices feature a distal recess that allows for optional use of the predicate Howmedica Osteonics Universal Distal Spacers and Howmedica Osteonics Universal Distal Hole Plugs.

The subject devices are single-use devices intended for use with any currently available Howmedica Osteonics acetabular component, unipolar component, or bipolar component. They may be used with any Howmedica Osteonics cobalt chromium alloy femoral head that can be mated with a 5°40' BG Taper. They may also be used with the Howmedica Osteonics Alumina C-Taper Heads when used with the Adapter Sleeve for V40 to C-Taper Ceramic Head. The devices continue to be compatible with the predicate distal ring centralizers. The femoral stem is intended for cemented fixation.

Indications:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Testing Summary

Analysis of stresses in the subject hip stems was performed to ensure that the incorporation of a distal recess does not adversely affect the integrity of the subject devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Debra Bing
Regulatory Affairs Manager
Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Re: K022555
Trade/Device Name: Accolade™ C Femoral Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: August 1, 2002
Received: August 2, 2002

Dear Ms. Bing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022555

Device Name: Accolade™ C Femoral Stems

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- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____ (Per 21 CFR 801.109)
(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022555